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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,798	07/02/2001	Carol A. Westbrook	21726/92526	1256
23644	7590	09/03/2003	EXAMINER	
BARNES & THORNBURG P.O. BOX 2786 CHICAGO, IL 60690-2786			MARTINELL, JAMES	
ART UNIT	PAPER NUMBER			
1631	12			

DATE MAILED: 09/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/897,798	WESTBROOK ET AL.	
	Examiner	Art Unit	
	James Martinell	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 June 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4-22 is/are pending in the application.
- 4a) Of the above claim(s) 4-11 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 12-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 02 July 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> | 6) <input type="checkbox"/> Other: _____ |

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Claims 4-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11 filed June 9, 2003.

The following references listed on form 1449 filed September 3, 2002 have not been considered because copies of these references are not in the file:

- (a) Xiang et al, Biotechnology Advances 18(1), 35-46 (2000),
- (b) Website: <http://www.image.llnl.gov>
- (c) Website: <ftp://ftp.resgen.com/pub/genefilters/>.

The disclosure is objected to because of the following informalities.

- (a) Appendix A is objected to because the pages are not numbered. Thus, it is not possible to know whether the pages in the file are in their proper order or whether all of the pages of Appendix A are in the file.

Appropriate correction is required.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Embedded hyperlink and/or other form of browser-executable code appear in at least the following locations:

- (a) page 7, line 9,
- (b) page 9, lines 3, 9, 13, and 19,
- (c) page 15, line 24,
- (d) page 16, line 15, and
- (e) page 17, line 9.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 12-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, incomplete and incomprehensible.

- (a) The recitation of "the molecules selected for an analysis of hematopoietic tissue" (claim 12) is vague, indefinite, and incomplete because the application does not define a set of molecules for such a purpose as is mentioned in the claim. A broad recitation of an intended purpose does not define or adequately describe the claimed collection of molecules.
- (b) The recitation of "related primates" (claim 13) is vague and indefinite because the instant application does not distinguish related primates from unrelated primates.
- (c) The recitation of "unique identifier" (claims 14 and 15) is vague, indefinite, and incomplete because the application does not identify the unique identifiers in Appendix A.
- (d) Claims 14 and 15 are incomplete in referring to Appendix A. There is no provision for a claim to refer to an appendix. In addition, the references given in Appendix A are to essential subject matter and are thus improper incorporations by reference (MPEP 608.01(p)).
- (e) The recitation of "analysis is to determine . . . engraft for transplantation" (claim 16) is vague and indefinite. A broad recitation of an intended purpose does not define or adequately describe the claimed collection of molecules.
- (f) Claims 16-22 are vague and indefinite because a broad recitation of an intended purpose does not define or adequately describe the claimed collections of molecules.
- (g) The recitation of "analysis is to expand . . . *ex vivo*" (claim 17) is vague, indefinite, and incomplete because a broad recitation of an intended purpose does not define or adequately describe the claimed collection of molecules.

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- (h) The recitation of "pharmacological manipulations" (claim 18) is vague and indefinite because the instant application does not distinguish pharmacological manipulations from non-pharmacological manipulations.
- (i) The recitation of "analysis is to determine . . . pharmacological manipulations" (claim 18) is vague, indefinite, and incomplete because a broad recitation of an intended purpose does not define or adequately describe the claimed collections of molecules.
- (j) The recitation of "analysis is to identify novel genes involved in hematopoiesis" is vague, indefinite, and incomplete because a broad recitation of an intended purpose does not define or adequately describe the claimed collections of molecules.
- (k) The recitation of "novel" (claim 19) is vague, indefinite, and incomplete. The meaning of the term changes with time in unknown ways.
- (l) The recitation of "involved" (claim 19) is vague and indefinite because the instant application makes no distinction between genes involved in hematopoiesis and genes not involved in hematopoiesis.
- (m) The recitation of "analysis is to diagnose hematopoietic cancers" (claim 20) is vague, indefinite, and incomplete because a broad recitation of an intended purpose does not define or adequately describe the claimed collections of molecules.
- (n) Claim 20 is vague and indefinite and incomprehensible because it is in improper form in that it contains more than one sentence (MPEP 608.01(m)) and depends from more than one claim, not in the alternative (MPEP 608.01(n)).
- (o) The recitation of "analysis is to determine if modifications altered expression levels of the cDNA molecules in the microchip" (claim 20) is vague, indefinite, and incomplete because a broad recitation of an intended purpose does not define or adequately describe the claimed collections of molecules.
- (p) The recitation of "10" (claim 20) is vague and indefinite because it is not understood what the term means within the context of the claim.

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- (q) The recitation of "modifications" (claims 20 and 21) is incomplete because there is no antecedent basis for the term.
- (r) Claim 20 is incomplete because it depends from cancelled claim 1.
- (s) The recitation of "modifications include gene therapy and treatment with growth factors" (claim 21) is vague and indefinite because the instant application does not define what is meant by "gene therapy" and there is no art recognized meaning for the term.
- (t) The recitation of "treatment with growth factors" (claim 21) is vague and indefinite because the instant application does not define the group "growth factors."
- (u) The recitation of "the data set comprising . . . analysis of hematopoietic tissue" (claim 22) is vague, indefinite, and incomplete because a broad recitation of an intended purpose does not define or adequately describe the claimed collections of molecules.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 13 contains new matter in the recitation of "related primates." There is o basis for the term in the application as filed.

Claims 12 –22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant application does not provide an adequate written description of the invention. A description of the actual nucleic

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acids on any microchip is not provided. The mere recitation of a desired or intended analysis for which microchips may be used does not provide a written description of the microchips themselves.

Claims 12-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant application does not teach how to make the microchips that are inadequately described as discussed in the immediately preceding rejection.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-22 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instant application does not teach a specific, substantial, and credible utility for the claimed invention. The discussion on pages 3-10 is not a disclosure of a specific, substantial, and credible utility nor would one of skill in the art recognize a readily apparent patentable utility for the claimed invention given the instant application. Broad statements regarding "data mining" and the possible later discovery of correlations of gene expression with certain (undisclosed) collections of cDNAs immobilized on microchips cannot substitute for a disclosure of an invention that has a real world use in its current (*i.e.* as of its filing date) form. See *Brenner v. Manson*, Supreme Court of the U.S., 148 USPQ 689 (1966)).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-22 are rejected under 35 U.S.C. 102(a) or (b) as being clearly anticipated by Research Genetics, Huntsville, AL. Applicants acknowledge that microchips that contain the claimed collections of

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cDNAs are old (see page 7, lines 15-25 and page 9, first full paragraph). The claims are broad enough to be embraced by the admittedly old microchips.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028.

PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



**James Martinell, Ph.D.
Primary Examiner
Art Unit 1631**